Interim Mandatory Patient Safety Reporting Requirements For General Hospitals

Patient Safety Reporting Initiative

Health Care Quality Assessment
Division of Health Care Quality and Oversight
New Jersey Department of Health and Senior Services

NEW JERSEY DEPARTMENT of HEALTH and SENIOR SERVICES

December 6, 2004

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Chapter I: Interim Procedures for Mandatory Reporting of Serious Preventable Adverse Events by General Hospitals

Mandatory Reporting of Serious Preventable Adverse Events

General hospitals have been required by rule for a number of years to report a wide range of events to the New Jersey Department of Health and Senior Services (Department). With the Patient Safety Act now in effect, the Department is developing rule amendments and new reporting systems to implement the new law. Under the law, every health care facility must report every serious preventable adverse event, defined as an adverse event that is preventable and results in a patient death, loss of a body part, disability, or loss of bodily function lasting for more than seven days or still present at the time of discharge. Preventable event means an event that could have been anticipated and prepared against, but occurs because of an error or other system failure.

Note: Other types of reportable events, including physical plant and operational interruptions, communicable diseases, and alleged criminal activities, are not covered by the Patient Safety Act and must continue to be reported according to existing procedures previously established by the Department.

Facilities Required to Report

On an interim basis, prior to adoption of rule amendments, a new reporting process is being implemented for all General Hospitals licensed pursuant to N.J.A.C. 8:43G.

Because general hospitals are already accustomed to reporting the events covered by the Patient Safety Act, the Department believes it would be advantageous to all parties to implement as soon as possible an interim system to redirect such reports from the acute care compliance enforcement process to the quality assessment program. Eventually with the adoption of the rules, it is anticipated that all reports of serious preventable adverse events, with the possible exception of those related to nursing homes, will be redirected to the quality assessment program.

Mandatory Reporting Process and Time Lines

General hospitals are required to report all serious preventable adverse events using the *Report of Serious Preventable Adverse Event in A New Jersey General Hospital Form*. Two versions of the form are available at www.NJ.gov/health/hcqo/ps. One version of the form is a computer-based form where event data can be entered and printed. The second version of the form is designed to be printed with the data entered by hand or typewriter. The *Event Report Form* is **due within two (2) Department business days of the discovery of the event, but in no case later than five (5) days after the occurrence of the event**.

The Report of Serious Preventable Adverse Event Root Cause Analysis (RCA) *Form* must be completed for each event subject to mandatory reporting and received by the Department **no later than 45 days following the initial report to the Department.** Two versions of this form are also available at www.NJ.gov/health/hcqo/ps.

The *Report of A Serious Preventable Adverse Event in A New Jersey General Hospital Form* should be faxed to the Department at (609) 530-4850. (Programming this fax number will prevent inaccurate transmission and protect confidentiality.) The *RCA Form* and any supporting documentation should be mailed in a confidential envelope to:

Patient Safety Reporting Initiative
Health Care Quality Assessment
New Jersey Department of Health and Senior Services
25 Scotch Road, Suite 10
Ewing, NJ 08628

Additional Information

For additional information, please contact the Patient Safety Reporting Initiative at (609) 530-7473.

Chapter II: Instructions for Completing the Serious Preventable Adverse Event Report Form

The *Report of Serious Preventable Adverse Event in A New Jersey General Hospital Form* is to be completed and transmitted only by an authorized facility representative. Completed forms are to be FAXED to the Department at (609) 530-4850 within two (2) Department business days of the discovery of the serious preventable adverse event, but in no case later than five (5) days after the occurrence of the event. The only exception pertains to objects erroneously retained in a patient after surgery, where the standard is no later than two (2) Department business days after discovery. Department business days mean Monday – Friday except for State holidays.

NOTE: A serious preventable adverse event is deemed *reported* to the Department only when the form is completed AND has been received by the Patient Safety Reporting Initiative. The Department will confirm receipt of the transmission by return Email or fax. Updated versions of the form may be submitted if new information becomes available. Updated forms should include all information, indicating which fields are revised.

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COMPLETING THE FORM

Please Type or Print All Information

- Indicate whether this is the first report of this event or a revision.
- IF a revision, give the DHSS Report Number which was assigned with the confirmation of receipt of the initial report from the Patient Safety Reporting Initiative.

NOTE: The Department anticipates that, to meet the reporting time frame, initial reports may be only partially complete and will be supplemented by updates.

SECTION A – GENERAL INFORMATION

1. Facility Identification

- List facility name, full address, and State of NJ license number.
- List the name, title, and contact information of the person completing the form.

2. Description of the Event

- Provide a short description of the event in narrative form, including how the event occurred and any medications, equipment, or conditions involved in the event.
- List the date and time of the event (note: if the event involves a surgical procedure, indicate the time that the procedure began).
- List the date and time the event was discovered.
- If the time of the event is unknown, list the time as “unknown.”

3. How Was the Event Discovered?

- Indicate how the event was discovered.
- If “other” is checked, provide a brief description of how the event was discovered.

4. Patient Information

Provide the following information about the patient:

- Indicate whether the patient received inpatient or outpatient care.
- Indicate how the patient was admitted (Emergency Department, Direct Admission, or Transfer from another facility). List the patient's billing number, the unique identifier for each admission.
- List the patient's medical record number or other identification used by the facility.
- List the patient's name and full address.
- List the patient's date of birth and gender.
- List the date of patient's admission to the facility or date of ambulatory encounter.
- List the patient's primary diagnosis, if applicable.
- Indicate the race and ethnicity of the patient, if known.
- If "other" is checked, provide a brief description of the race or ethnicity.

5. Types of Serious Preventable Adverse Events

Using the definitions below, indicate the general classification and type of the serious preventable adverse event. Use only one category.

A. Care management-related events include, but are not limited to:

1. Patient death, loss of body part, disability, or loss of bodily function lasting more than seven days or still present at discharge, associated with a medication error (e.g., errors involving the wrong drug, wrong dose, wrong patient, wrong time, wrong rate, wrong preparation, wrong route of administration, etc.);
2. Patient death, loss of body part, disability, or loss of bodily function lasting more than seven days or still present at discharge, associated with a hemolytic reaction due to the administration of ABO-incompatible blood or blood products;
3. Maternal death, loss of body part, disability, or loss of bodily function lasting more than seven days or still present at discharge associated with labor or delivery in a low- risk pregnancy while in a health care facility;
4. Patient death, loss of body part, disability, or loss of bodily function lasting more than seven days or still present at discharge associated with hypoglycemia, the onset of which occurs while the patient is being cared for in the health care facility;
5. Death or kernicterus associated with failure to identify and treat hyperbilirubinemia in a neonate while the neonate is a patient in a health care facility;
6. Stage three or four pressure ulcers acquired after admission of the patient to a health care facility. Excludes progression from Stage two to Stage three if Stage two was recognized upon admission;
7. Patient death, loss of body part, disability, or loss of bodily function lasting more than seven days or still present at discharge, associated with spinal manipulative therapy provided in a health care facility;
8. Other patient care management-related adverse preventable event resulting in patient death, loss of a body part, disability, or loss of bodily function lasting for more than seven days or still present at the time of discharge not included within the definitions above.

B. Environmental events include, but are not limited to:

1. Patient death, loss of body part, disability, or loss of bodily function lasting more than seven days or still present at discharge, associated with an electric shock while being cared for in a health care facility. Excludes events involving planned treatments, such as electric counter shock (heart stimulation);
2. Any incident in which a line designated for oxygen or other gas to be delivered to a patient contains the wrong gas or is contaminated by toxic substances and results in patient death, loss of body part, disability or loss of bodily function lasting more than seven days or still present at discharge;
3. Patient death, loss of body part, disability, or loss of bodily function lasting more than seven days or still present at discharge, associated with a burn incurred from any source while in a health care facility;
4. Patient death, loss of body part, disability, or loss of bodily function lasting more than seven days or still present at discharge, associated with a fall while in a health care facility;
5. Patient death, loss of body part, disability, or loss of bodily function lasting more than seven days or still present at discharge, associated with the use of restraints or bedrails while in a health care facility;
6. Other environmentally-related adverse preventable events resulting in patient death, loss of a body part, disability, or loss of bodily function lasting for more than seven days or still present at the time of discharge not included within the definitions above.

C. Product or device-related events include, but are not limited to:

1. Patient death, loss of body part, disability, or loss of bodily function lasting more than seven days or still present at discharge, associated with use of generally detectable contaminated drugs, devices, or biologics provided by the health care facility, regardless of the source of contamination and/or product;
2. Use or function of a device in patient care in which the device is used or functions other than as intended, including but not limited to catheters, drains, and other specialized tubes, infusion pumps, and ventilators;
3. Intravascular air embolism that occurs while the patient is in the facility. However, this does not include deaths or disability associated with neurosurgical procedures known to present a high risk of intravascular air embolism;
4. Other product or device-related adverse preventable event resulting in patient death, loss of a body part, disability, or loss of bodily function lasting for more than seven days or still present at the time of discharge not included within the definitions above.

D. Surgery-related events include, but are not limited to:

1. Surgery initiated (whether or not completed) on the wrong body part;
2. A surgical procedure (whether or not completed) intended for a different patient of the facility, but initiated on this patient;
3. A wrong surgical procedure initiated (whether or not completed) on a patient;
4. Retention of a foreign object in a patient after surgery, excluding objects intentionally implanted as part of a planned intervention and objects present prior to surgery that were intentionally retained;
5. Inter-operative or post-operative (i.e. within twelve hours) coma, death or other serious preventable adverse event for any ASA Class I inpatient or any same day

surgery patient (all ASA classes). Includes all patient deaths, comas or other serious preventable adverse events in situations where anesthesia was administered; the planned surgical procedure may or may not have been carried out;

6. Other surgery-related adverse preventable event resulting in patient death, loss of a body part, disability, or loss of bodily function lasting for more than seven days or still present at the time of discharge not included within the definitions above.

E. Patient protection-related events include, but are not limited to:

1. Discharge of an infant to the wrong person, excluding patient abductions;
2. Any patient death, loss of body part, disability, or loss of bodily function lasting more than seven days associated with patient elopement;
3. Patient suicide or attempted suicide while in a health care facility. However, this does not include deaths or disability resulting from self-inflicted injuries that were the reason for admission to the health care facility;
4. Other patient protection-related adverse preventable event resulting in patient death, loss of a body part, disability, or loss of bodily function lasting for more than seven days or still present at the time of discharge not included within the definitions above.

6. *For Medication Errors Only*

- If 5.A.1 is checked, indicate the type of medication error.
- If "other" is checked, provide a short description of the medication error.
- List the brand name and/or generic name of the medication.

7. Where Was the Patient When the Event Occurred?

- Indicate the location of the patient when the event occurred. Check only one location.
- If "other" is checked, provide a short description of the location.

8. Immediate Corrective Action(s) Taken

- Provide a description of the immediate corrective action taken in response to the event. The description provided should include the specific procedures implemented, if any, to reduce the likelihood of recurrence of this event. List any additional reports provided to other organizations or agencies (e.g., equipment manufacturers, pharmaceutical manufacturers, and professional oversight boards) concerning this event.

Chapter III: FORM-Report of Serious Preventable Adverse Event in A New Jersey General Hospital

See following page.

New Jersey Department of Health and Senior Services

REPORT OF SERIOUS PREVENTABLE ADVERSE EVENT IN A NEW JERSEY GENERAL HOSPITAL

NJDHSS INTERNAL USE ONLY
Report No.

This form must be completed for any serious preventable adverse event, which results in death or loss of a body part, or disability or loss of bodily function lasting more than seven (7) days or present at discharge.

Is this a revision of an earlier report to the Patient Safety Reporting Initiative for the same event? ☐ Yes ☐ No	If yes, give DHSS Report Number:	Facility Internal Tracking Number of this incident, if known:

SECTION A - GENERAL INFORMATION

1. FACILITY IDENTIFICATION

Facility Name: _____ Facility License No.: _____

Facility Street Address: _____ County: _____

City: _____ State: _____ Zip Code: _____

Name of Person Submitting: _____ Telephone No.: _____

Title or Position: _____ Fax No.: _____

Email Address: _____

2. PLEASE SUPPLY A SIMPLE AND CLEAR DESCRIPTION OF THE EVENT OR SITUATION YOU ARE REPORTING:

Incident Information:

Incident Date: _____ Time: _____ ☐ AM ☐ PM

Date you became aware of event: _____ Time: _____ ☐ AM ☐ PM

3. HOW WAS EVENT DISCOVERED?

☐ 1. Report by staff/physician
☐ 2. Report by family/visitor
☐ 3. Report by patient
☐ 4. Assessment of patient after event
☐ 5. Review of chart/record
☐ 6. Other: _____

4. PATIENT INFORMATION

☐ Inpatient or ☐ Outpatient

Admission through: ☐ ED ☐ Direct ☐ Transfer

Patient Billing Number: _____

Patient Name: _____ Medical Record No.: _____

Street Address: _____ County: _____

City: _____ State: _____ Zip Code: _____

Date of Birth: _____ Gender: _____

Admission Date or Date of Ambulatory Encounter: _____

Primary Diagnosis: _____

Race:

☐ Caucasian ☐ Amer. Indian/Alaskan Native ☐ Native Hawaiian/Pacific Islander ☐ Other: _____
☐ Black ☐ Asian ☐ Unable to Determine

Ethnicity: ☐ Non-Hispanic/Unable to Determine ☐ Hispanic

New Jersey Department of Health and Senior Services

REPORT OF SERIOUS PREVENTABLE ADVERSE EVENT IN A NEW JERSEY GENERAL HOSPITAL

Continued

NJDHSS INTERNAL USE ONLY
Report No.

SECTION B - EVENT DETAILS

5. TYPES OF SERIOUS PREVENTABLE ADVERSE EVENTS *(Check only one)*

A. CARE MANAGEMENT EVENTS in a Health Care Facility

- ☐ 1. Patient death/harm due to a medication error
- ☐ 2. Patient death/harm due to a hemolytic reaction due to the administration of ABO-incompatible blood or blood products
- ☐ 3. Maternal death/harm due to labor/delivery in a low-risk pregnancy
- ☐ 4. Patient death/harm due to hypoglycemia
- ☐ 5. Patient death/harm due to failure to identify and treat hyperbilirubinemia in neonates
- ☐ 6. Stage 3 or 4 pressure ulcers acquired after admission
- ☐ 7. Patient death/harm due to spinal manipulative therapy
- ☐ 8. Other event causing patient death or harm that lasts seven days or is present at discharge

B. ENVIRONMENTAL EVENTS in a Health Care Facility

- ☐ 1. Patient death/harm due to an electric shock
- ☐ 2. Any event in which a line designated for oxygen/other gas to be delivered to a patient contains the wrong gas or is contaminated by toxic substances
- ☐ 3. Patient death/harm due to a burn incurred from any source
- ☐ 4. Patient death/harm due to a fall
- ☐ 5. Patient death/harm due to the use of restraints or bedrails
- ☐ 6. Other event causing patient death or harm that lasts seven days or is present at discharge

C. PRODUCT OR DEVICE EVENTS in a Health Care Facility

- ☐ 1. Patient death/harm due to the use of contaminated drugs/devices/biologics
- ☐ 2. Patient death/harm due to the use/function of a device in patient care in which the device is used/functions other than as intended
- ☐ 3. Patient death/harm due to intravascular air embolism
- ☐ 4. Other event causing patient death or harm that lasts seven days or is present at discharge

D. SURGERY-RELATED EVENTS

- ☐ 1. Surgery performed on the wrong body part
- ☐ 2. Surgery performed on the wrong patient
- ☐ 3. Wrong surgical procedure performed on a patient
- ☐ 4. Retention of a foreign object in a patient after surgery or other procedure
- ☐ 5. Intraoperative or immediately post-operative coma or death in an ASA Class I (hospital) or any ASA Class patient (ambulatory surgery center)
- ☐ 6. Other event causing patient death or harm that lasts seven days or is present at discharge

E. PATIENT PROTECTION EVENTS in a Health Care Facility

- ☐ 1. Infant discharged to the wrong person
- ☐ 2. Patient death/harm due to patient elopement
- ☐ 3. Patient suicide/attempted suicide
- ☐ 4. Other event causing patient death or harm that lasts seven days or is present at discharge

New Jersey Department of Health and Senior Services

REPORT OF SERIOUS PREVENTABLE ADVERSE EVENT IN A NEW JERSEY GENERAL HOSPITAL

Continued

NJDHSS INTERNAL USE ONLY
Report No.

6. IF 5.A.1 WAS SELECTED, COMPLETE THIS SECTION:

What type of medication error occurred? (Check all that apply)

- ☐ Wrong Patient
- ☐ Wrong Drug
- ☐ Wrong Dose
- ☐ Wrong Route
- ☐ Wrong Frequency
- ☐ Wrong Time
- ☐ Omission
- ☐ Administration After Order Discontinued/Expired
- ☐ Wrong Diluent/Concentration/Dosage Form
- ☐ Monitoring Error
- ☐ Other: _____

Brand/Product Name (If Applicable): _____

Generic Name: _____

7. WHERE WAS THE PATIENT WHEN THE EVENT OCCURRED? *(Check only one)*

- ☐ Patient Room
- ☐ Emergency Department
- ☐ Radiology
- ☐ Laboratory
- ☐ Operating Room
- ☐ Nursery
- ☐ Recovery Room
- ☐ Rehabilitation Areas
- ☐ In Transit
- ☐ ICU / CCU / TCU
- ☐ NICU
- ☐ Hallway or Other Common Area
- ☐ Other:

_____

8. IMMEDIATE CORRECTIVE ACTION(S) TAKEN:

Chapter IV: Instructions for Completing the Serious Preventable Adverse Event Root Cause Analysis (RCA) Form

The *Report of Serious Preventable Adverse Event in A New Jersey General Hospital: Root Cause Analysis (RCA) Form* must be completed by the hospital for each serious preventable adverse event reported to the Department. The completed *RCA form*, with any supporting documentation, must be received by the Department **no later than 45 days following the date of submission of the initial report to the Department.** Information should be sent to:

Patient Safety Reporting Initiative
Health Care Quality Assessment
New Jersey Department of Health and Senior Services
25 Scotch Road, Suite 10
Ewing, NJ 08628

RCA Team Requirements

The RCA is to be performed by a multi-disciplinary team of the hospital or the system to which the hospital belongs. It is to be submitted in the format described below.

RCA Process Requirements

The RCA process consists of three components: Facts of the Event, Causality, and Action Plan. All of these components must be included for the RCA to be considered acceptable. The components are defined as:

Facts of the Event

a. Provide specific details of the event including the date, time, and day of the week;

b. Where the event occurred;

c. Describe the elements of the event clearly and in chronological order. Identify all staff involved by title and function. Give enough detail that a person not familiar with the event can understand what happened;

d. Describe the adverse event and how the patient was affected;

e. Did a similar event occur in the past three years in this facility? If yes, state when it occurred and describe what corrective actions, if any, were implemented.

Causality

a. Using the *Rules of Causation* guidelines attached (see Appendix), describe all the direct causes of the event and all procedural or systemic causes that contributed to the event's occurrence.

Action Plan

a. Describe the corrective actions that the facility will implement to prevent a similar incident from occurring in the future. These actions should be specific and address each cause listed (i.e., someone who is not a member of the RCA team should be able to understand what to do next);

b. Describe the time frame for implementation of each corrective action;

c. Describe how each corrective action's effectiveness will be measured and monitored.

Purpose of the RCA

The purpose of the RCA is to uncover the factor(s) that led to and caused a serious preventable adverse event. It is not intended to assign blame to individuals or to organizations. Prior research has shown that most adverse events are due to systemic failures rather than intentional individual acts or professional incompetence. Only by determining the underlying systemic causes of an adverse event can an effective action plan be formulated to minimize the chances of reoccurrence.

For Example:

Patient A received the wrong medication, which led to a reaction, which required medical intervention and a prolonged hospitalization.

In analyzing the event, an investigator not familiar with RCA determined that the cause was, "The nurse was tired and grabbed the wrong medication by mistake." The investigator then recommended that the nurse be counseled not to come to work tired.

This approach, however, does not address any systemic causes. A more appropriate analysis using RCA might find that there had been a flu outbreak and that the nurse had worked three double shifts that week. The analysis might also note that two medications with almost identical packaging were involved and that one of the lights in the nursing station had been out for over a week making it more difficult to read the label. In light of these additional factors, a more effective action plan could be formulated to address all the causes contributing to the adverse event.

In performing the RCA and formulating the corrective action plan, the RCA Team should draw on such resources as evidence-based medicine literature, best-practices reports, Joint Commission Resources (a not-for-profit subsidiary of the Joint Commission on the Accreditation of Healthcare Organizations), or other resources, if appropriate.

COMPLETING THE FORM

Please Type or Print All Information

SECTION A – GENERAL INFORMATION

1. Facility Identification

- List facility name, full address, and State of NJ license number.
- List the name, title, and contact information of the person completing the form.

SECTION B –INCIDENT INFORMATION

2. Description of the Event

- List the date and time of the event (note: if the event involves a surgical procedure, indicate the time that the procedure began).
- If the time of the event is unknown, list the time as "unknown."
- List the patient's medical record number, billing number (if appropriate), and full name.

SECTION C –ROOT CAUSE ANALYSIS

3. Select Root Cause

- Indicate from your analysis of the direct, procedural, and systemic causes of the adverse event the specific processes involved as contributing factors.

4. What Were the Contributing Factors to the Event?

- Indicate from your analysis of the direct, procedural, and systemic causes of the adverse event if any of the listed activities or characteristics were contributing factors.

5. Evaluate Impact of Event for Patient

- Review the impact of the event for the patient (check all that apply).

6. Describe Root Cause Analysis

- Provide a comprehensive description of the analysis process and findings, including specific actions for implementation, time frame for implementation, and measurement and monitoring goals for evaluating the effectiveness of the planned intervention. Note any specific recommendations from the Patient Safety Committee.

- Describe the facts of the event, causality, and action plan as described under *RCA Process Requirements* on page 1 of this chapter.

- List any reports to other organizations or agencies (e.g., equipment manufacturers, pharmaceutical manufacturers and professional oversight boards) concerning this event.

Chapter V: FORM-Report of Serious Preventable Adverse Event in A New Jersey General Hospital: Root Cause Analysis (RCA)

See following page.

New Jersey Department of Health and Senior Services

REPORT OF SERIOUS PREVENTABLE ADVERSE EVENT IN A NEW JERSEY GENERAL HOSPITAL: ROOT CAUSE ANALYSIS (RCA)

NJDHSS INTERNAL USE ONLY
Report No.

This form must be completed for any serious preventable adverse event, which results in death or loss of a body part, or disability or loss of bodily function lasting more than seven (7) days or present at discharge.

SECTION A - GENERAL INFORMATION

1. FACILITY IDENTIFICATION

Facility Name: _____ Facility License No.: _____

Facility Street Address: _____ County: _____

City: _____ State: _____ Zip Code: _____

Name of Person Submitting: _____ Telephone No.: _____

Title or Position: _____ Fax No.: _____

Email Address: _____

SECTION B - INCIDENT INFORMATION

2. INCIDENT DATE: _____ Time: _____ ☐ AM ☐ PM

Date Initial Report Sent to Patient Safety Reporting Initiative: _____ DHSS Report Number (Assigned by DHSS): _____

Medical Record Number: _____ Patient Billing Number: _____

Patient Name: _____

SECTION C - ROOT CAUSE ANALYSIS

3. SELECT ROOT CAUSE (Select all that apply):

☐ Behavioral assessment process
☐ Patient identification process
☐ Care planning process
☐ Orientation & training of staff
☐ Supervision of staff
☐ Communication among staff members
☐ Adequacy of technical support
☐ Physical environment
☐ Control of medications (Storage/access)
☐ Physical assessment process
☐ Patient observation procedures
☐ Staffing levels
☐ Competency assessment/credentialing
☐ Communication with patient/family
☐ Availability of information
☐ Equipment maintenance/management
☐ Security systems and processes
☐ Labeling of medications
☐ Other: _____

New Jersey Department of Health and Senior Services

REPORT OF SERIOUS PREVENTABLE ADVERSE EVENT IN A NEW JERSEY GENERAL HOSPITAL: ROOT CAUSE ANALYSIS (RCA) (Continued)

NJDHSS INTERNAL USE ONLY
Report No.

4. WHAT WERE THE CONTRIBUTING FACTORS TO EVENT (Select all that apply):

- ☐ Team factors
- ☐ Task factors
- ☐ Patient characteristics
- ☐ Medical Device
- ☐ Procedures
- ☐ Equipment
- ☐ Patient record documentation
- ☐ Laboratory and diagnostics
- ☐ Work environment
- ☐ Staff factors
- ☐ Organizational/management
- ☐ Medications
- ☐ Transportation
- ☐ Home Care
- ☐ Imaging and X-rays
- ☐ Other (Specify): _____

5. EVALUATE IMPACT OF EVENT FOR PATIENT (Select all that apply):

- ☐ Loss of limb(s)
- ☐ Loss of digit(s)
- ☐ Loss of body part(s)
- ☐ Loss of organ(s)
- ☐ Loss of sensory function(s)
- ☐ Loss of bodily function(s)
- ☐ Disability - physical or mental impairment
- ☐ Additional laboratory testing or diagnostic imaging
- ☐ Other additional diagnostic testing
- ☐ Other (Specify): _____
- ☐ Additional patient monitoring in current location
- ☐ Visit to Emergency Department
- ☐ Hospital admission
- ☐ Transfer to more intensive level of care
- ☐ Increased length of stay
- ☐ Minor surgery
- ☐ Major surgery
- ☐ System or processes delay care to a patient
- ☐ To be determined
- ☐ Death

6. DESCRIBE ROOT CAUSE ANALYSIS:

(Attach the RCA.)

Appendix: 5 Rules of Causation

These 5 *Rules of Causation* are provided as a resource to assist the facility in conducting the Root Cause Analysis (RCA) of a Serious Preventable Adverse Event. In preparing the RCA, consider these principles.

Rule 1: ***Root Cause Statements must clearly indicate the "cause and effect" relationship.***

When describing why an event has occurred, RCA statements should show the link between the root cause and the adverse outcome. Each link should be clear to both the RCA Team and others.

Examples: WRONG: A resident was fatigued.
CORRECT: The level of the resident's fatigue increased the likelihood that she misread the instructions, which led to incorrect tube insertion.

Rule 2: ***Negative descriptions should not be used in Root Cause Statements.***

Negative descriptions are often a substitute for more accurate and clear descriptions. Words like *carelessness* and *complacency* are poor choices because they are broad, negative judgments that do little to describe the actual conditions or behaviors that led to the mishap.

Examples: WRONG: Poorly trained nurse.
CORRECT: The level of the nurse's training increased the likelihood that he misunderstood the IV Pump controls, which led to missing steps in the programming of dose and rate.

Rule 3: ***Each human error must have a preceding cause.***

Many adverse events involve a set of events and errors. For each human error in the causal chain, there must be a corresponding cause. Similar to "Rule 1," the links need to be clear and obvious to the RCA Team and others. It is the cause of the error, not the error itself, which leads to productive prevention.

Examples: WRONG: The lighting level was low.
CORRECT: The level of lighting in the patient's room increased the probability that the tripping hazard would not be seen, which led to the patient's fall and….

Rule 4: ***Violations of procedure are not root causes; they must have a preceding cause.***

Procedural violations are not directly manageable. Instead, it is the cause of the procedural violation that can be managed. The goal is to identify the positive and negative incentives that created the informal norm or accepted way of doing things.

Examples: WRONG: The pharmacy technician did not follow IV fluid mixing procedures.
CORRECT: A lack of encouragement and oversight of pharmacy employees by Management created an informal atmosphere where missed training and bypassing procedures was acceptable practice.

Rule 5: ***Failure to act is only causal when there was a pre-existing duty to act.***

The duty to act may arise from standards and guidelines for practice or other duties to provide patient care. The failure to act is judged on the duty to act at the time the error occurred.

Example: A doctor's failure to prescribe a cardiac medication after a myocardial infarction can only be causal if he/she was required by well-established guidelines to prescribe the medication in the first place.

These rules have been adapted from material provided by the: VA National Center for Patient Safety (www.patientsafety.gov).